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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,317	05/25/2000	Boris Shkolnik	CRD0852	5734

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EXAMINER

DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 02/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/578,317

Applicant(s)

SHKOLNIK, BORIS

Examiner

Matthew F DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. This application contains claim 17 drawn to an invention nonelected with traverse in Paper No. 3. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 11 is rejected under 35 U.S.C. 102(e) as being anticipated by Maria van Erp (6102891).

Maria van Erp discloses a balloon catheter with a catheter body comprising an outer tubular member having a tubular wall (ref #. 2) and having a lumen extending throughout the length of the outer tubular member, the tubular member further having a proximal end and a distal end, an inflatable balloon (ref #. 3) having a main body portion, a proximal portion, and a distal portion, the proximal portion and the distal portion extending from the main body portion, the distal portion of the balloon being bonded to the tubular member near the distal end of the tubular member and the proximal portion of the balloon being bonded to the tubular member proximal to the distal portion of the balloon, where the balloon is made of polyolefin, further comprising a coupling member (ref #. 26) having a lumen extending therethrough, the coupling

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member being mounted on the proximal end of the tubular member and the lumen of the coupling member communicating with the lumen of the tubular member, and at least one aperture (ref # 20) for purging air from the lumen of the catheter body, the aperture extending radially through the wall of the tubular member at a point proximal to the proximal portion of the inflatable balloon. (Figures 1, 2, 6 and Column 2, lines 49-58, and entire reference).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maria van Erp as applied to claim 11 above, and further in view of Rydell (USPN 4811737), and Burns et al. (USPN 5176698).

Maria van Erp disclosed the claimed invention but fails to disclose the balloon being coupled to a syringe and the specific size of the apertures.

Rydell discloses the specific size of venting ports in a balloon catheter, where the size of the hole is between 0.0005 to 0.0015 inches. (Column 3, lines 22-37 and Column 4, lines 10-24).

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Burns et al. discloses a balloon catheter being coupled to a syringe for injection fluid into the balloon and using a gas permeable balloon to increase the air vented through the balloon and decrease the chance of releasing air in the blood vessel.

At the time of the invention it would have been obvious to one of ordinary skill in the art to combine Maria van Erp with Rydell and Burns et al. because it is well known in the medical art to use a syringe to inject fluid into a catheter to inflate a balloon (as taught by Burns et al.), and the motivation for making the apertures 0.0005 to 0.0015 is because this size would have been able to permit air to be vented and preclude the outflow of liquid as well as prevent the inflow of air back in the catheter as taught by Rydell col. 4, lines 10-24.

Therefore, it would have been obvious to combine Maria van Erp with Burns et al. and Rydell to obtain the invention as specified in claims 11-14.

4. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maria van Erp and Burns et al. and Rydell as applied to claims 11-14 above, and further in view of Carlblom (USPN 5637365) and Follmer et al. (5728065).

Maria van Erp and Burns et al. and Rydell disclosed the claimed invention having a balloon being made of a polymer and the polymer being polyolefin, but never described the characteristics of the balloon, such as the balloon being gas permeable, Maria van Erp and Burns et al. and Rydell failed to disclose placing the balloon in a protective tube.

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Carlbom discloses that polyolefin is a "gas-permeable material." Column 10, lines 18-49.

Follmer et al. discloses the use of a constraining member (ref #. 200), to be placed over the inflatable balloon

At the time of the invention, it would have been obvious to a person of ordinary to make the inflatable balloon out of a gas permeable material by Carlbom and to place the balloon in a constraining member taught by Follmer et al. with the invention of Maria van Erp and Burns et al. and Rydell.

The suggestion/motivation for making the balloon out of a gas permeable material is taught by Maria van Erp, and Burns et al. and further supported by Carlbom col. 10, lines 18-40, where Carlbom teaches that polyolefin is a polymer that is gas permeable, and the motivation for the protective tube or constraining member was to limit the radial expansion of the balloon but at the same time expanding the balloon allowing for a greater rate of gas and liquid to be flushed out of the vent hole, under normal inflation pressure (Follmer et al. column 7, line 45-column 8, line 14).

Therefore, it would have been obvious to combine Maria van Erp and Burns et al. and Rydell with Carlbom and Follmer et al. to obtain the invention as specified in claim 1-16.

Response to Arguments

5. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 1-703-872-9302 for regular communications and 1-703-872-9303 for After Final communications.

Matthew DeSanto
Art Unit 3763
February 3, 2003



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